UNDERSTANDING ORD AND PROGRAM PRIORITY SETTING

INTRODUCTION

The United States Environmental Protection Agency (the Agency) is both a regulatory and a scientific agency; it is one of only a few federal organizations that operates in this capacity. The environmental laws that form the legal basis for the Agency's regulatory activities or rulemaking also authorize its scientific efforts in both research and assessment. Agency research and assessment efforts are primarily housed in the Office of Research and Development (ORD). The research and assessment efforts provide the foundation for scientifically defensible environmental policies, programs and regulations.

THE AGENCY'S OFFICE OF RESEARCH AND DEVELOPMENT

Unlike the Program and Regional Offices of the Agency, ORD has no direct regulatory function; rather, ORD is responsible for informing the regulatory processes of these offices. Through the development of scientific and technical information, ORD strengthens the Agency's science base by providing the Agency's Program and Regional Offices with sound information for use in the development and implementation of environmental policies, regulations and practices. Comprising seven national laboratories and centers across the country, ORD's broad scope encompasses both human and ecological health (see Figure 1 below).

Figure 1. Alignment of ORD Labs/Centers with Risk Paradigm

ORD is organized around the principles of *risk assessment* and *risk management*. Risk assessment is the processes of evaluating the nature, magnitude and likelihood of an adverse effect following exposure to a stressor(s). For example, ORD's services may be called upon both to assess the risk associated with exposures at a Superfund site and to assist in managing the risk by informing the determination of a clean up level. In addition to helping shape and prioritize ORD's research agenda, these principles are an inherent part of ORD's organizational structure. Figure 2, below, is a diagram of the risk assessment /risk management paradigm. The risk assessment process involves hazard identification, dose-response assessment, exposure assessment and risk characterization.

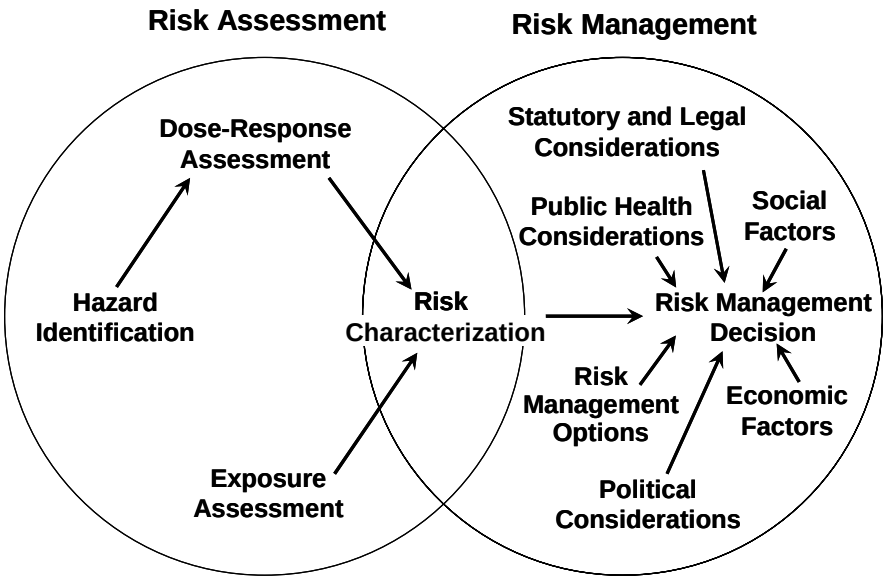

Figure 2. Risk Paradigm

ORD cannot address every concern related to the environment but must be selective in deciding which problems are the highest priorities. Some research, such as studies relating to children risks, is required by law; other activities, e.g., assessment of clean-up levels after Hurricane Katrina, are initiated in response to specific environmental exigencies. Thus, ORD's research can be broadly viewed from two perspectives: *scientific and programmatic*. The scientific perspective includes cross program research with broad scientific application to advance environmental science while the programmatic perspective includes research and assessments with direct application to high priority, Agency needs and mandates. ORD research must be scientifically relevant, but it must also be responsive to regulatory and policy decisions.

The framework for organizing research within ORD is drawn from *the Agency's Strategic Goals,* which are summarized in Text Box 1. These goals identify the overall environmental results, such as cleaner air, that the Agency is working to attain. The Agency uses these goals to systematize the way in which it prioritizes, plans and implements research; reports research findings and products; and budgets programs. Each goal is linked to key environmental statutes. For example, the first goal, *Clean Air,* is aligned with the Clean Air Act. Similarly, the second goal, *Clean and Safe Water,* responds to the mandates of the Clean Water Act and the Safe Drinking Water Act. Accordingly, research performed under a particular goal supports the regulatory actions mandated by the corresponding legislation.

Text Box 1. The Agency's Strategic Goals

1) Clean Air
2) Clean and Safe Water
3) Land Preservation and Restoration
4) Healthy Communities and Ecosystems
5) Compliance and Environmental Stewardship

As discussed in ORD's Strategic Plan, these goals drive the research performed in ORD. For each of the goals, ORD's labs and centers have committed to reaching certain milestones and delivering specific products within a given time period, thus providing a mechanism for measuring tangible progress toward the completion of long-term goals. This explicit accountability grew out of the Government Performance and Results Act (GPRA) passed by Congress in 1993. Consequently, these Agency goals are sometimes referred to as "GPRA Goals."

In addition to developing and implementing policy, ORD is a problem-solving organization. Three principal elements (*Research*, *Leadership* and *Scientific and Technical Assistance*) encompass ORD's activities.

Research. Research provides the Agency with the necessary information and technology for detecting, abating and avoiding environmental problems. ORD's research emphasis changes as priorities shift, as new data surfaces, as court-ordered deadlines are met or as fiscal budgets change. However, ORD strives to build and maintain research programs that are both relevant to scientific problems and responsive to Agency needs. ORD's intent is to create an integrated and coherent program—not a collection of disconnected projects.

Leadership. ORD provides vital leadership in environmental research, and its scientists are proactive in the scientific community at many levels. Within the Agency, ORD managers and scientific staff help shape the research agenda by contributing to planning and coordination exercises and participating in the development of ORD research. Scientists represent the Agency in workshops and task forces to address major risk assessment, public health and environmental issues. Outside the Agency, ORD scientists influence the direction and priorities of environmental research worldwide, participating in collaborative efforts at the national and international level by serving as members of international planning committees and review panels, advisory

boards of other major agencies and organizations and as adjunct faculty members at major universities across the nation.

Scientific and Technical Assistance. As part of ORD's mission, scientists and staff respond to diverse requests for scientific advice and technical consultation, both within and outside the Agency. ORD provides technical support to Agency Program and Regional Offices on scientific matters by participating in Agency workgroups, by developing testing and risk assessment guidelines and by providing training. At the national and international level, ORD scientists provide guidance by organizing scientific workgroups and symposia and by serving in professional and scientific societies and by working on publication boards. ORD's goal is to establish partnerships with the public, private and educational sectors and to assist them in setting and achieving environmental goals. ORD has established a number of technical training and developmental opportunities for senior scientist as well as post doctoral candidates and students. Sharing ORD skills and knowledge serves as an important catalyst for scientific and technological progress and enhances the ability of other organizations to protect human health and the environment.

PRIORITY SETTING

Multi-year planning allows ORD to consider the future strategic direction of the Agency and determine where scientific investigation can contribute. Annual research planning takes place within the Agency as part of the federally mandated planning and budgeting process. ORD pays special attention to research and activities required to fulfill legislative mandates, court orders and Agency GPRA commitments. Setting priorities is a critical part of ORD's planning and budgeting process, both long-term and annually, and draws on multiple sources to create robust programs. Among these are

- Agency and ORD strategic plans;
- Customer/user needs; and
- Outside peer review and consultation.

Priority setting also takes into consideration scientific feasibility, ongoing efforts, budgetary constraints and ORD's ability to make a contribution relative to other programs and institutions.

Multi-year plans (MYPs) outline the major areas of ORD programs by establishing the direction both from a long-term strategic perspective and an annual GPRA perspective. MYPs provide information to assure the relevance, quality and performance of our programs by:

- assisting and supporting decisions during budget formulation;
- clarifying the key scientific questions being addressed within a program;
- identifying key results and the products being developed; and
- demonstrating how ORD's programs contribute to Agency outcomes and strategic goals;

Although the information contained in the MYPs is of interest to a wide variety of audiences, their primary purpose is planning and communication within ORD. The information in the MYP is also useful for communicating ORD's vision within the Agency, with other organizations and with anyone interested in the direction of ORD research and assessment efforts.

MYPs are written by a lead author and a writing team. The writing team consists of laboratory/center experts who collaborate with the Program and Regional Office, ORD's Office of Science Policy (OSP) and Office of Resource Management and Administration (ORMA). Guidance on shifts between MYPs or shifts within MYPs is provided by the ORD Executive Council (EC) to ensure consistency across all ORD programs and priorities.

Five basic assumptions drive MYP development:

1. MYPs plan efforts for at least five years beyond the current President's Budget to provide long-term direction;
2. MYPs identify and address major areas or activities critical to Programs and Regions in order to establish priorities within a program and across ORD;
3. MYPs reflect an annual budget that does not exceed the current President's Budget to provide a realistic limit to the amount of work that can be completed in a given year;
4. Although the total resources in an MYP remain constant, the distribution of resources across ORD laboratories and centers and the relative emphasis in any particular area are likely to change over the 5 year planning period and therefore are not assumed to be constant; and
5. MYPs are updated biennially, or on an as-needed basis, to account for changes in Agency direction, the current state-of-the-science, resource changes and progress in implementing the plan.

ORD MYPs consist of three parts: a narrative to orient and inform the readers of the writing team's intent and the logic that supports the MYP, flow diagrams that show the critical path to achieving each long term goal and a table listing performance measures (APGs/APMs).

The narrative provides the overall context for the program and describes the logic used and decisions made in framing the MYP. The narrative also provides background information and describes both the rationale for selecting specific activities and the sequencing of the work. Lastly, the narrative, includes quantitative information relating to the magnitude of the research effort described, as well as trend information to inform the reader of how the relative emphasis will shift as the program matures.

Three factors that influence research priority include (1) the potential to support effective risk reduction, (2) EPA Program and Regional Office priorities and (3) the completion status of ongoing efforts. Currently, there is also an increasing focus on the

Office of Management and Budget (OMB) Research and Development (R&D) investment criteria. These criteria include the following:

> *Relevance* - R&D programs must be able to explain why investment in this area is important, relevant and appropriate. R&D Programs must have well conceived plans that identify program goals and priorities and identify relevance to national and customer needs.
>
> *Quality* - R&D programs must justify fund allocation to ensure quality R&D. R&D Programs must also document how quality is maintained.
>
> *Performance* - R&D programs must have the plans and management processes in place to monitor and document how well the investment is performing. Program managers must define appropriate outcome measures and milestones that can demonstrate tangible progress towards goals and assess the direction of future funding.

These investment criteria specifically require federal research programs to

- demonstrate complete plans with clear goals and priorities;
- articulate potential public benefits/justify funding methods;
- define appropriate output and outcome measures, schedules and decision points; and
- assess program relevance, quality and performance periodically through prospective and retrospective review by independent experts.

The MYPs serve to assist ORD in addressing the requirements listed under the first three bullets above. To address the fourth bullet, ORD's Board of Scientific Counselor (BOSC) provides external independent peer review of these programs and the MYPs.